UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of	*	
KORANGY RADIOLOGY ASSOCIATES, P.A., Trading as BALTIMORE IMAGING CENTERS, A corporation,	*	ADMINISTRATIVE COMPLAINT FOR CIVIL MONEY PENALTY
And		FDA Docket: 2003H-0432
AMILE A. KORANGY, M.D., An individual	*	

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POST-HEARING BRIEF OF RESPONDENTS

Now come Respondents, Korangy Radiology Associates, P.A., t/a Baltimore Imaging Centers ("BIC") and Amile A. Korangy, M.D. ("Dr. Korangy"), by their attorneys, Henry E. Schwartz, and Henry E. Schwartz LLC, and file the following Post-Hearing Brief. All references herein are intended to apply to both Respondents, unless specified to the contrary.

I. Federal statute requires that FDA develop and apply procedures for the issuance of civil money penalties ("CMPs" or "fines"), and the absence of such procedures invalidates the CMPs issued in the instant case.

The federal statute providing authority for FDA regulation of mammography equipment is 42 USC 263b ("the Mammography Act"). The authority for the issuance of CMPs for non-compliance with the Act and its implementing regulations is 42 USC 263b(h), subsection (4) of which requires that "[t]he Secretary shall develop and implement procedures with respect to when and how each of the sanctions is to be imposed under (the preceding) paragraphs (1) through (3)."

It is uncontroverted, and in fact, admitted by FDA, that the agency has never issued guidance with respect to the requirement to develop and implement procedures for when and how the sanction authority (including the use of CMPs) is to be utilized. Testimony of Michael P. Devine, Tr. at p.13. In plain English, the FDA has ignored the statutory requirement that it develop and implement guidance regarding the issuance of CMPs. There exist no rules, policies or procedures with respect to the issuance of such fines. The FDA has left the "when and how" of the use of such sanctions to arbitrary determination, despite the clear statutory mandate to the contrary.

As a result, the imposition of CMPs in this case (even if they had not been issued at the statutory maximum) is illegal. The FDA's authority is granted by the statute, and expressly limited by the statute. That the issuance of fines without any standards is, by definition, arbitrary and capricious, will be addressed in the next section. The point herein being made is that FDA had no authority to issue fines without the requisite standards having been developed and implemented.

As a subsidiary matter, it is to be noted that 42 USC 263b(h)(4) also requires the development of procedures to provide for notice to the "owner or operator" of the facility. In the instant case, delivery of notice was accepted upon evidence that it had been "received by the facility," (Testimony of Michael P. Devine, Tr. at p.17), and it did not matter "who" received it. Id., at 18, 19 and 20. Despite the fact that Dr. Korangy was personally charged with $1,800,000.00 in fines, no effort was made to restrict delivery to him, or to ensure that he actually received a copy of the delivered document intended to notify him of the existence of a violation that required remediation. Whether or not this is considered "fair," it does not meet the statutory mandate to develop procedures to provide notice to the "owner or operator" of the facility.

Again, the failure to follow statutorily-mandated procedures invalidates the FDA action in this case, and such failure may not be cured through a substitution of judgment on the part of the Administrative Law Judge for the agency. There remain no procedures in place to meet the statutory mandate.

II. Federal regulations place the burden of proof of the appropriateness of the CMPs on the FDA's Center for Radiologic Health, and the failure of the Center to meet this burden invalidates the CMPs issued in the instant case.

Governing federal regulations, at 21 CFR 17.33, mandate that "the Center" must, at hearing, prove the appropriateness of the penalties issued, by a preponderance of the evidence. This was not done in the instant case. The following is a discussion of what factors the Center "proved" in the instant case with respect to the appropriateness of 386 counts of $10,000.00 maximum fines:

a. FDA did not consider mitigation. The fact that Respondents ordered a new machine even before being told that their existing machine would not warrant recertification was not considered relevant. Testimony of Michael P. Devine, Tr. at p.24.

b. FDA testified that it considered Respondents' ability to pay, but indicated that the only consideration given to that issue was to "determine" that Respondents could indeed afford $3,800,000.00 in fines because they had "several different locations." Id., at 25. No other factors or information regarding ability to pay were considered before issuing the CMPs. Id., at 26.

c. FDA did consider the length of time of violation and the number of violative procedures in determining the appropriateness of the penalty. Id., at 30. However, this testimony, if not false, is patently bizarre, in view of the penalties issued more recently

by FDA in In Re Ecumed Health Group, et al, FDA Docket: 2004H-0322. (Admitted through Judicial Notice). In that case, filed by FDA on July 19, 2004, the respondents were accused of performing 1,201 inappropriate procedures, over a time-period spanning 17 months. Compare to the instant case, where the charges consist of 192 procedures spanning a two-month period. In both cases, the FDA issued, to each Respondent, one $10,000.00 fine for performing procedures without current certification. In the instant case, however, each procedure also brought a $10,000.00 fine against each Respondent. In Ecumed, the per-procedure fine was $1,000.00. Accordingly, in Ecumed, considerably more egregious alleged violations (in both number and time) brought penalties a mere tenth of those levied against Dr. Korangy and Korangy Radiology Associates, P.A. ("Intent" is not a factor favoring distinction, as evidenced by Paragraphs 30 and 31 of the FDA complaint in Ecumed, which charged the respondents in that case with knowledge of the alleged violations). Therefore, FDA testimony in the instant case that the agency "considered" the length of time of violations and number of procedures in determining the penalty is not credible, and in fact, is meaningless.

No evidence was presented to indicate that any other factors were considered by FDA in issuing the fines in the instant case. Accordingly, the Center has not met its regulatory burden to demonstrate, by a preponderance of the evidence, that the penalties issued in this case were appropriate. Instead, the evidence presented by FDA clearly indicates that the maximum penalties that FDA believed were allowed by law were levied, and no serious consideration was ever (prior to or during the hearing) given to the "appropriateness" of such amounts, despite the requirement of 21 CFR 17.33 for the Center to prove such appropriateness.

Accordingly, the fines issued by FDA against Respondents' must be rejected in total for the failure to meet the regulatory burden of proof. The Administrative Law Judge may not substitute his discretion for that of the agency in this matter, as it is the Center that is required by regulation to prove its case. It has not done so.

III. FDA issued CMPs in this case that are grossly disproportionate to the offenses charged, and thus are invalid as violative of the 8th Amendment to the United States Constitution.

As indicated above, FDA in this case issued what it considered to be maximum possible fines in the total amount of $3,800,000.00, and did so without adopting statutorily mandated procedures, and without even considering those issues that would have allowed it to meet its regulatory burden to prove the appropriateness of the penalties. Further, FDA issued fines greatly in excess (by a factor of 10) of those levied in Ecumed, a case where more egregious violations were alleged.

The 8th Amendment to the United States Constitution contains an "Excessive Fines Clause," which provides that "excessive fines [shall not be] imposed." United States v. Bajakajian, 524 U.S. 320, at 321 (1998). This protection "limits the Government's power to extract payments, whether in cash or in kind, as punishment for some offense. Id, citing Austin v. United States, 509 U.S. 602, 609-610. That this

constitutional protection applies to civil money penalties issued by the federal government has been accepted by the 9th Circuit. See, Vasudeva v. United States, 214 F.3d 1155, 1161 (9th Cir., 2000).

Under the 8th Amendment, "[a] punitive forfeiture violates the Excessive Fines Clause if it is grossly disproportional to the gravity of the offense that it is designed to punish." Id. The 4th Circuit Court of Appeals reads Bajakajian as considering the nature and extent of the criminal activity, its relation to other crimes, its penalties, and the harm caused as being relevant to the determination of "grossly disproportional. United States v. Ahmad, 213 F. 3rd 805, at 813, 815 (4th Cir. 2000).

In the instant case, the imposition of over $3,800,000.00 in fines against a business entity and its sole owner constitutes "excessive" fines that are "grossly disproportionate to the gravity of the offense alleged." FDA has indicated that it was not its intention to put Dr. Korangy and the corporation out of business. The FDA is not trying to "shut down facilities," but is "trying to get them to correct violations." Testimony of Michael P. Devine, Tr. p.15. It is not the intention of FDA to drive Respondents in this case out of business. Id. at 26. To that end, the FDA would consider credible documentation of the inability to pay the fines levied. Id. at 29.

Despite the FDA's stated position on the impact of the CMPs, FDA has not lowered the fines, even though Dr. Korangy and the corporation have provided documentation to the clear effect that, singly or in combination, they do not have, nor do they generate, enough resources to pay millions of dollars in fines.

Further, the CMPs are grossly disproportionate in view of the above discussion of the fines levied by FDA in the Ecumed case.

Nor is there evidence that FDA considered, in setting the CMPs, the lack of profit to Respondents in performing mammography procedures (documented to FDA), Respondents' standing as a "Small Business Entity," and Respondents' attempted mitigation through the purchase of a new mammography equipment in advance of a final ACR recommendation.

For all the reasons set forth above, the $3.8+ million CMPs issued in the instant case are grossly disproportionate to the offenses charged, and should be stricken as violative of the 8th Amendment to the United States Constitution.

IV. Conclusion.

For the reasons set forth above, the CMPs issued in the instant case violate federal regulation, statute, and the United States Constitution, and therefore must be reversed in total. The Administrative Law Judge has no authority to revise or modify the CMPs in this case, because the (a) the FDA has in place no statutorily mandated guidelines to apply for that purpose, and (b) Federal regulations require the Center to meet the established burden of proof in this case, and it has not done so.

Respectfully submitted on behalf of Respondents, by:

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 2nd day of December, 2004, a copy of the foregoing Post-Hearing Brief of Respondents was mailed, first class, postage prepaid, to Complainant's Counsel, as follows:

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